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**AFTER FINAL
EXPEDITED PROCEDURE**

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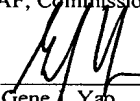
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of H. Hofland, D. Lamons, and X. Meng
Application No. 09/996,838 Group No. 1632
Filed November 29, 2001 Examiner J. Epps-Ford
Natural and Anionic Colloidal Particles for Gene Delivery

(Attorney Docket No. P 23,643-A USA)

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to Box AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on Monday, September 18, 2006.


Gene Yao

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Commissioner for Patents
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SUMMARY OF INTERVIEW PURSAUNT TO 37 CFR §§ 1.2 AND 1.133

Sir:

On August 10, 2006, the undersigned, on behalf of the applicants, conducted an interview by telephone with the Examiner to discuss the Examiner's final Action, dated April 14, 2006. The discussion addressed all of the claims as well as the following documents: U.S. Patent No. 6,379,966 to Monahan et al.; U.S. Patent No. 6,287,591 to Semple et al.; and U.S. Patent Application Publication No. US 2003/0026841 to Trubetskoy et al.

Subsequent to the interview, applicants filed on August 14, 2006 a Reply to the final Action. The Reply included claim amendments that were recommended by the Examiner. Thereafter, the Examiner issued on August 21, 2006 a communication entitled "Interview Summary".

The present Summary is being submitted for the purpose of satisfying the requirement under 37 CFR §§ 1.2 and 1.133. The following is a summary of the above-referenced discussion and is not meant to supplant arguments made in the aforementioned Reply.

The undersigned submitted that the Examiner's Section 102(e) rejection of Claims 18 to 23 and 30, which are directed to a colloid and a method for using the same, as being anticipated by Monahan et al. is in error because the claims distinguish over the disclosure of Monahan et al. in that they define a colloid comprising a DNA-containing complex in which cationic polymers or cationic lipids thereof have been modified using citraconic anhydride or N-hydroxysuccinimide acetate to render such polymers or lipids neutral or anionic. By contrast, Monahan et al. does not disclose a colloid comprising such a complex. Instead the colloid of Monahan et al. comprises a complex having DNA and cationic polymers which are not modified. Instead, the complex is further enveloped by a layer of anionic polymers.

The undersigned submitted that the Examiner's Section 103(a) rejection of Claims 1, 7, 11, 14, 15, 18 to 23, and 28 to 30, which are directed to the above colloid and method for using the same and to a method for making such a colloid, based on the combined disclosures of Semple et al., Trubetskoy et al., and Monahan et al. is in error also. It was asserted


that a *prima facie* case of obviousness has not been established in that it has not been explained by the Examiner how one skilled in the art would have had any expectancy that the claimed invention would be successful. This argument was raised previously in a Reply filed on January 23, 2006 but the Examiner failed to address it in her final Action; this is understandable because there is evidence of record to the contrary. It was noted that the present claims recite that the colloid of the present invention contains a complex in which cationic compounds have been converted into neutral or anionic compounds. Trubetskoy et al., however, states that adding anionic compounds to a complex comprising DNA and cationic compounds could destabilize the complex. One skilled in the art, therefore, would have basis for concluding that the practice of the present invention would result in a destabilization of the complex and, therefore, of the colloid. Accordingly, one skilled in the art would not have had any expectation that the claimed invention would be successful.

In the Action, the Examiner rejected Claims 1, 7, 11, 14, 15, and 18 to 32 under the written description requirement of Section 112, first paragraph, because she considered the claims, as amended in the January 23, 2006 Reply, as comprising new matter in that they allegedly redefined the recited process as being one which converted a precursor colloid comprising a single DNA-containing complex into a colloid comprising a multiplicity of DNA-containing complexes. During the interview, the undersigned submitted that the amendment did not include new matter because it is evident, based on descriptions in the application, that the precursor colloid could contain more than one DNA-containing complex.

In addition to the above, the Examiner considered the aforementioned claims to include new matter because they allegedly no longer required that the resulting colloid have DNA which is sequestered within the complex. The Examiner recommended that the claims be amended to clarify that the DNA in the resulting colloid be sequestered within the complex. Such an amendment was submitted in the Reply filed on August 14, 2006.

The Examiner requested also that the claims be amended to clarify that the polymers that are reacted with the reagent are cationic. Such an amendment was also submitted in the Reply filed on August 14, 2006.

Respectfully submitted,



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